DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 1, 2015

Stealth Therapeutics, Inc.
c/o Mr. Gary Syring
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, WI 53589

Re: K141146
Trade/Device Name: Invisiport™
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, implanted, intravascular infusion port and catheter
Regulatory Class: II
Product Code: LJT
Dated: March 31, 2015
Received: April 2, 2015

Dear Mr. Syring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141146

Device Name
Invisiport

Indications for Use *(Describe)*
The Invisiport is indicated for any patient requiring repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products, or the sampling of blood, or for power injection of contrast media when used with a power-injectable Huber needle or infusion set.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K141146

STEALTH
THERAPEUTICS INC.

510(k) Summary

This summary is provided to support the 510(k) notification for the subject Invisiport manufactured for Stealth Therapeutics, Inc.

Contact Name: Samuel Adams
Company Name: Stealth Therapeutics, Inc.
Address: 101 Nob Hill Road, Suite 100
Madison, WI 53713
Phone: (608) 217-2685

Date Summary Prepared: April 29, 2015

Trade Name: Invisiport™

Common Name: Implantable Infusion Port

Classification Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
21 CFR 880.5965, Product Code LJT

Predicate Device: K110407, Invisiport™, manufactured for Stealth Therapeutics, Inc.

Product Description

The predicate device and subject device are injection ports. An open ended radiopaque catheter is pre-attached to the predicate and subject devices.

This 510(k) pre-market notification supports the addition of a catheter size variation to the predicate device. The modification to the predicate device to create the subject device is a change in the attached catheter. The predicate device attached catheter is substantially a 6 Fr catheter. The subject device attached catheter is a 4.4 Fr catheter. This change affects the attached catheter.

Intended Use of the Device

The intended use of the subject device is the same as the predicate device:

> The Invisiport™ is indicated for any patient requiring repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products, or the sampling of blood, or for power injection of contrast media when used with a power-injectable Huber needle or infusion set.

Summary of Technological Characteristics

The following table provides a side-by-side comparison of the subject device to the predicate device.

Table 1: Substantial Equivalence Technical Characteristics			
Feature	**Subject Device**	**Predicate Device**	**Comment**
Indications for Use	The Invisiport™ is indicated for any patient requiring repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products, or the sampling of blood, or for power injection of contrast when used with a power-injectable Huber needle or infusion set.	The Invisiport™ is indicated for any patient requiring repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products, or the sampling of blood, or for power injection of contrast when used with a power-injectable Huber needle or infusion set.	Same
Power Injection	Yes	Yes	Same
Power Injection Input Pressure Limit	300 psi	300 psi	Same
Power Injection Flow Rate of 11.8 cP fluid	4.5 ml/sec	5 ml/sec	Both devices are power injectable at pressures up to 300 psi. The subject device with a 4.4 Fr catheter supports a maximum of 4.5 ml/sec power injection flow rate of an 11.8 cP fluid with a 300 psi power injection limit. The predicate device with a 6 Fr catheter supports a 5 ml/sec power injection flow rate of an 11.8 cP fluid with a 300 psi power injection limit. The difference in flow rate is due to the power injector's ability to support a flow rate with an 11.8 cP fluid at 300 psi applied pressure. The smaller 4.4 Fr catheter supports a lower flow rate at this 300 psi pressure limit.
Port Access	Hospital/clinic licensed health care provider	Hospital/clinic licensed health care provider	Same
Location of implant	Peripheral or thoracic	Peripheral or thoracic	Same
Design	Septum/port with integrated catheter	Septum/port with integrated catheter	Same
Attached Catheter Length	53.3 cm	53.3 cm	Same
Catheter Diameter	1.47 mm (4.4 French)	2.0 mm (6 French)	A smaller diameter catheter variation is available.

Performance tests to demonstrate substantial equivalency

The risks presented by a smaller catheter diameter have been evaluated. Applicable tests recommended in the FDA Guidance: Guidance on 510(k) Submissions for Implanted Infusion Ports and the tests performed to support substantial equivalence of the predicate device was evaluated. The following table identifies the tests performed on the subject device and results.

Table 1: Subject Device Performance Testing Summary		
Test	**Summary of Requirement**	**Result**
1. Visual	Verify markings on OD with numbers at applicable increments.	Pass
2. Dimensional	Verify critical dimensions.	
3. Clearance Parameters	Verify clearance volume.	
4. Port to Catheter Connection Test	Lateral and Axial (Dry): No leaks after static load. Lateral and Axial (Wet): No leaks after port exposed to wet medium and a static load. Cycle Lateral and Axial: No leaks after cyclic load. Creep: No leaks after minimal load. Load to Failure, Axial and Lateral.	Pass
5. Port Leak Test	Withstand static pressure without leaking for both intermittent and continuous pressure testing.	Pass
6. Power Injection Flow Rate	Verify flow rate under power injection conditions with a set viscosity and flow.	Pass

All tests passed with acceptable results on the subject device.

No clinical data are required to confirm substantial equivalence of the subject device. Bench evaluations of potentially affected performance are adequate to support substantial equivalence.

Conclusions

The subject device is a modification of the predicate device and meets all established acceptance criteria for performance testing. The intended use and technology of the subject device is the same as the predicate device.